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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
SULLIVAN, DANIELLE D	
ART UNIT	**PAPER NUMBER**
1616	

NOTIFICATION DATE	DELIVERY MODE
02/23/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/581,367	RAMPOLDI ET AL.	
	Examiner	Art Unit	
	DANIELLE SULLIVAN	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/02/2006 and 4/11/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-18 are pending examination.

Note: Claim 1 is a product by process claim. The claims are drawn to a "gabapentin granulate" product. The presence of PEG in the granulating process is not a factor in the final product obtained. Therefore the claim reads on a gabapentin granulate.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation of “PEG having a melting point comprised between 50 and 80 ^{o}C” is vague. The recitation of PEG is an abbreviation which can have different meanings. Therefore, the metes and bounds of the claim cannot be deciphered. If the meaning of PEG is limited to polyethylene glycol having a specific weight the claim must be clarified to encompass the particular structure and/or chemical name. The term PEG is an abbreviation of polyethylene glycol which causes the claim not to satisfy definiteness. The abbreviation should precede or follow the term polyethylene glycol.

Claims 2-4, 9, 11 and 14 contain the recitation of "% by weight" without specifying what the recitation is relative to.

Claim 4 recites the limitation "wherein the gabapentin is present in quantities equal to 98% by weight, the PEG being 2%" in the recitation of a “gabapentin granulate

obtained by granulating with PEG having a melting point comprised between 50 and 80 ^{o}C". There is insufficient antecedent basis for this limitation in the claim. As noted claim 1 is a product by process claim. The product is a gabapentin granulate and the presence of PEG (polyethylene glycol) is lacking in the product recited. Therefore, the recitation of a particular range of PEG lacks antecedent basis. Furthermore, it is unclear what "PEG being 2%" means because it is unclear what the % is relative to.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The factors considered in the written description requirement are (1) *level of skill and knowledge in the art,* (2) *partial structure,* (3) *physical and/or chemical properties*, (4) *functional characteristics alone or coupled with a known or disclosed correlation between structure and function*, and the (5) *method of making the claimed invention.*

While all of the factors have been considered, only those required for a *prima facie* case are set forth below.

The specification does not disclose PEG having a melting point comprised between 50 and 80 ^{o}C or disclose where the compounds can be obtained. However, examples use PEG 6000, PEG 4000 and PEG 1000.

The claims are drawn to a property rather than a particular structure.

University of Rochester v. G.D. Searle & Co., 69 USPQ2d 1886 (Fed.Cir. 2004), states that the description must convey what the compound is, not just what it does (see page 1895). A review of the language of the claim indicates that these claims are drawn to the action of "PEG having a melting point comprised between 50 and 80 ^{o}C" rather than a particular structure. Therefore there are no structure disclosed in claims, therefore the written description requirement is not satisfied.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-5, 7-9, 12, 13, 15, 17 and 18 are rejected under 35 U.S.C. 102(e) as being anticipated by Manikandan et al. (US 2006/0039968).

Manikandan et al. disclose a stable gabapentin tablet prepared by granulation [0025]. Any binder compatible with gabapentin may be used [0029]. Other excipients

selected from disintegrants, fillers, stabilizers, lubricants, colorants and glidants my be added [0031].

Claims 1-13 and 15-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Spireas (US 7,056,951).

Spireas disclose solid dosage forms comprising gabapentin and polyethylene glycol prepared by granulation (Table 3-5). Examples 16 and 23 disclose formulations comprising 74% gabapentin, 1.8% polyethylene with remainder being additives. The formulations can be capsules or tablets (column 3, lines 25-29; column 13, lines 7-19).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 6, 10, 11 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Manikandan et al. (US 2006/0039968) in view of Ochiai et al. (7,192,608).

Applicant's Invention

Applicant claims a gabapentin granulate as discussed in above 102(e) rejection. Claims 6, 10, 11 and 16 further define the granulate under capsule form.

Determination of the scope and the content of the prior art

(MPEP 2141.01)

The teachings of Manikandan et al. are addressed in above 102(e) rejection.

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

Manikandan et al. do not teach the use gabapentin granulates are formulated as capsules. It is for this reason that Ochiai et al. is combined.

Ochiai et al. teach a method of manufacturing drug granules by granulation (abstract). A drug having high water solubility is formed into tablets along with a small amount of excipients or a single crystal is filled in a capsule to form a capsule preparation (column 1, lines 48-52). The water soluble drug includes gabapentin (column 4, line 61; column 6, line 36). The release control film may contain additives, including plasticizers selected from polyethylene glycol (column 24, lines 29-31).

Finding of prima facie obviousness

Rationale and Motivation (MPEP 2142-2143)

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Manikandan et al. and Ochiai et al. to further include formulating the granulates as capsules. One would have been motivated to include capsule form because Ochiai et al. teach a method of manufacturing drug granules by granulation filled in a capsule with drugs selected from gabapentin. Therefore, it would have been obvious to one of ordinary skill in the art to formulate the gabapentin granulates into a capsule.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Manikandan et al. (US 2006/0039968) in view of Ochiai et al. (7,192,608) and in further view of Patel et al. (US 2003/0064097).

Applicant's Invention

Applicant claims a gabapentin granulate as discussed in above 102(e) rejection. Claim 14 specifies the granulate comprises 2-25% PEG (polyethylene glycol).

Determination of the scope and the content of the prior art

(MPEP 2141.01)

The teachings of Manikandan et al. and Ochiai et al. are addressed in above 103(a) rejection.

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

Manikandan et al. and Ochiai et al. do not teach 2-25% polyethylene glycol. However, Ochiai et al. teaches that polyethylene glycol may be added as a plasticizer. It is for this reason that Patel et al. is joined.

Patel et al. teach solid carriers for improved delivery of hydrophobic active ingredients in pharmaceutical compositions (abstract). The hydrophobic drugs delivered include gabapentin [0036] and [0037]. The dosage forms may be prepared by granulation in the form of a tablet or capsule [0186]. The coating contains 10-25% of a plasticizer selected from polyethylene glycol 400 [0215].

Finding of prima facie obviousness

Rationale and Motivation (MPEP 2142-2143)

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Manikandan et al., Ochiai et al. and Patel et al. to further include polyethylene glycol in an amount of 10-25%. One would have been motivated to include this range because Patel et al. teach 10-25% of a plasticizer selected from polyethylene glycol. One would have been motivated to manipulate ranges during routine experimentation to discover the optimum or workable range since Patel et al. provides the general range.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Danielle Sullivan whose telephone number is (571) 270-3285. The examiner can normally be reached on 7:30 AM - 5:00 PM Mon-Thur EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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